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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,640	11/27/2001	Thomas George Gant	PC11042A	8096

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PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER

SMALL, ANDREA D SOUZA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 05/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant No.

09/993,640

Applicant(s)

GANT ET AL.

Examiner

Andrea D Small

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

I. Applicant's Response:

- (a) Applicants response filed 2/20/2003 has been received and entered as paper no. 7.
- (b) Pending Claims: 1-37.

II. Remarks:

(a) Double Patenting Rejection:

Applicants have traversed the rejection for the following reasons:

- (i) Applicants argue that “the Examiner is using the ‘764 patent as prior art”, and suggests that the only instance where the patent disclosure may be used in a double patenting rejection is in the form of a dictionary to understand the meaning of terms employed in the claims; and
- (ii) Applicant argue that there is no motivation or suggestion provided, specifically that the Examiner has failed to provide reasons why one of ordinary skill in the art would conclude that the invention is an obvious variation of the invention in the ‘764 patent.

The Examiner respectfully disagrees.

First, *In re Boylan*, stated that the specification can always be used as a dictionary to learn the meaning of a term in the patent claim. However, *In re Vogel* held that those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. Additionally, the court stated that one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent claims and may be considered.” The court further asserted that “this use of the disclosure is not in contravention of the cases forbidding its

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use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.” Instantly, the ‘764 patent is not being employed as prior art, rather it is being relied on where it provides support for the obvious variations of the patented claim. Claims 9-23 in the ‘764 patent recite specifically the compounds instantly claimed and their pharmaceutically acceptable salts. The portion of the ‘764 patent specification, col. 11, lines 38-50, relied on in the previous office action provides supports for the ‘pharmaceutically acceptable salts’ variations of the claimed invention, and thus *may* be considered. As stated by the *Vogel* court, “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.” Thus, the employment of the ‘764 disclosure is proper and supports the double patenting rejection.

Second, there is ample motivation and suggestion provided in the ‘764 patent. Column 11, lines 38-50 of the patent provides for the obvious variations of the claimed invention, i.e., the pharmaceutically acceptable salts of the claimed compounds, especially those that are preferred. Thus, one of ordinary skill in the art would be motivated to made additional pharmaceutically acceptable salts of the compounds claimed in the ‘764 patent as the patent specifically indicates the preferred pharmaceutically acceptable salts embodiments of the compounds, consequently providing a reasonable expectation of success in the end utility of said compounds. Therefore, the double patenting rejection is proper and maintained.

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III. Maintained Rejection:***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9, compounds 1 and 2 and claims 10-23 of U.S.

Patent No. 6,235,764. Although the conflicting claims are not identical, they are not patentably distinct from each other because

The instant claims are drawn to various salts of the compound 3-(4-bromo-2,6-difluorobenzyloxy-5-[3-(4-pyrrolidin-1-yl-butyl)-uriedo]-isothiazole-4-carboxylic acid amide, pharmaceutical composition and method of using the same. The difference between that claimed instantly and the reference is that the instant claims claim specific salts of the compounds that are not claimed. However, the reference teaches that pharmaceutically acceptable salts of the compound may be made, see claim 10, and the reference lists various salt forms that can be made, see col. 11, lines 38-50. Therefore, one of ordinary skill in the art would be motivated to make additional salt forms of this known compounds with the specific suggestion and teaching

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that the reference provides that the claimed salt form can be made and provide a reasonable expectation of success in being employed for the same utility.

IV. New Rejections:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims rejected under 35 U.S.C. 103(a) as being unpatentable over Larson, et al (US 6,235,764 B1).

Determination of the scope and content of the prior art (MPEP §2141.01)

The instant claims are drawn to various salts of the compound 3-(4-bromo-2,6-difluorobenzyloxy-5-[3-(4-pyrrolidin-1-yl-butyl)-uriedo]-isothizole-4-carboxylic acid amide, pharmaceutical composition and method of using the same.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

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The difference between the prior art and the instant claims is that the prior art does not specifically disclose the species as instantly claimed.

Finding of prima facie obviousness---rationale and motivation (MPEP §2142-2413)

However, the reference teaches that pharmaceutically acceptable salts of the compound may be made, see claim 10, and the reference lists various salt forms that can be made, see col. 11, lines 38-50. Therefore, one of ordinary skill in the art would be motivated to make additional salt forms of this known compounds with the specific suggestion and teaching that the reference provides that the claimed salt form can be made.

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the inventor of this application, and is therefore, not the invention "by another", or by antedating the applied art under 37 CFR 1.131.

V. Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small, whose telephone number is (703) 305-0811. The examiner can normally be reached on Monday-Thursday from 8:30 AM - 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

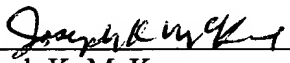
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Joseph.McKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy

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published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1234

Andrea D. Small, Esq.
May 1, 2003



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626
Technology Center 1